MENTOR

ENGINEERING STUDY: HTV PARTICLE SPECIFICATION ANALYSIS

The signatures below indicate the best technical expertise has been presented herein to certify this ENGINEERING STUDY REPORT determines the effect of varying particle sizes on ------ ---------- ------ gel shell physical properties.

Study Submitted By:

Signature	Date
Printed Name, Title, Department	

Study Approved By:

Engineering Signature	Date
Printed Name, Title, Department	

Q & RA Signature	Date
Printed Name, Title, Department	

R & D Signature	Date
Printed Name, Title, Department	

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1.0 PURPOSE

This report provides results and analysis from Engineering Study Protocol HS33.980831.01, "HTV Particle Specification Analysis". This report documents the effect of particle defects, of a specific size, on the physical properties of sterilized HTV gel shells. This report determines how increasing particle size affects shell physical properties for HTV gel shells. The results of this report will determine a dimensional particle specification for all HTV gel ---------- shells.

This report has been prepared under the relevant guidelines and procedures as established by the Mentor Engineering Department.

2.0 SCOPE

This report affects all ----------HTV gel shells. It provides documented evidence of the effect o---------- e physical properties of ---------- HTV gel shells.

3.0 RESPONSIBILITIES

3.1 Originator

A. Prepare and write this study and the final report.

B. Assemble the test data and attachments during execution of this study. Review the data and attachments for accuracy and acceptable completion.

3.2 Management

A. Review and approve this study and the final report according to the certification requirements indicated on the cover pages.

B. Support the execution of this study by providing or arranging for the necessary resources and materials.

4.0 BACKGROUND

This report has been prepared as a follow-up report to HS33.990715.02, "Engineering Study: HTV Particle Analysis Summary Report". The purpose of that report was to determine the effect of the presence of particles in an un-sterilized, un-filled HTV gel shell and the resulting physical properties. The data gathered and analyzed in that

study concluded that particles in the shell do not affect the shell physical properties to the point in which shells will fail the validation specifications for tensile strength and elongation. Engineering Study Protocol HS33.990831.01 was executed to perform the same physical testing, except on shells, which have been exposed to gel, the historical heat exposure for worst-case gel shells, and sterilized. Coupons were utilized instead of finished devices to track the location of the particle on the shell efficiently. The study was executed by this method to duplicate the assembly process without assembling finished devices.

5.0 METHOD

A sample size of 30 shells was used to test the physical properties of each particle size category. Four distinct particle size categories were tested. They are:

1. Shells with particles that are less than 0.010" in diameter.
2. Shells with particles that are between 0.011" to 0.015" in diameter.
3. Shells with particles that are between 0.016" to 0.020" in diameter.
4. Shells with particles that are between 0.021" to 0.025" in diameter.

HTV inspectors collected shells for each category, which the location of the particle was either the top or radius of the shell. Historically, the top and radius of a HTV gel shell are thinner than the base; thus particles on the top and radius of the shell will represent particles on the thinnest part of the shell. HTV Inspectors completed Protocol Attachment I, which verified the size of the particle and location of the particle. Deviation #1 occurred during execution of this attachment (see Attachment I). The protocol was deviated from because the size of the particle was verified as being in the correct size category instead of being measured. See Attachment II.

The shells were exposed to the maximum heat and time during the Assembly process to duplicate the time and temperature exposure to devices during the process. The worst case time and temperature exposure for a HTV ---------- shell is the inner shell of a Becker device. Procedure 500314 governs the assembly of the inner shell and all shells were exposed to a minimum of -----minutes at ----°- and a minimum of - minutes at-----°- . Length of time and heat exposure during cure was verified to -onform to Procedure 500314. See Attachment III.

GSL operators cut the test coupons with the particle in the critical area of the coupon (the middle of the coupon) under Special Project # 3057. See Attachment IV.

The coupons were placed on a gel-cure tray and covered with gel. The coupons were cured under normal curing conditions per PROC 600852 and were cured with production lot number 200840. Length of time and heat exposure during cure was verified to conform to Procedure 600852. See Attachment V.

The coupons were ---------- sterilized per PROC 000218 under normal sterilization conditions. PROC 000218 governs the longer ---------- sterilization cycle for the ---------- and represented the worst case sterilization cycle. The coupons were also 2X sterilized to represent the worst-case sterilization cycle. See Attachment VI.

All coupons were cleaned and tested for tensile strength and elongation per TM 000019 under Special Project # 3057. See Attachment VII.

Engineering Study Protocol HS33.990831.01 stated the following acceptance criteria.

Physical property test results for tensile strength and elongation will be analyzed using the current validation acceptance criteria for HTV shells. The current acceptance criteria for tensile strength and elongation are that the mean of a population minus three standard deviations produces a value which passes finished device testing acceptance criteria. Finished device testing acceptance criteria for elongation and tensile strength are as follows:

FINISHED DEVICE TEST	SPECIFICATION
TENSILE STRENGTH	----------
ELONGATION	----------

6.0 RESULTS

There were a total of four test groups representing four distinct particle size groups tested for tensile strength and elongation. The means and standard deviations for each group were calculated with the following results.

Table 1

Physical Test	<0.010"	0.011"-0.015"	0.016"-0.020"	0.021"-0.025"
Tensile Strength				
- Average	5.213	5.112	4.825	4.784
- St. Deviation	0.867	0.553	0.809	0.858
Elongation				
- Average	675.914	689.800	621.010	600.553
- St. Deviation	46.233	*49.793*	42.596	55.442

**Non-normal distribution calculation*

A sample size calculation was performed to confirm the number of coupons tested conformed to the required sample size population. All test coupon sample sizes met the established requirements. The results are as follows.

Table 2

Sample Size Calculation	<0.010"	0.011"-0.015"	0.016"-0.020"	0.021"-0.025"
Sample Size For Tensile Strength	29	29	31	30
Required Sample Size For Tensile Strength	25.6	12	26	29.4
Conforms?	YES	YES	YES	YES
Sample Size For Elongation	29	29	31	30
Required Sample Size For Elongation	6	8.5	6	9.3
Conforms?	YES	YES	YES	YES

To analyze the test coupon sample groups utilizing the mean minus 3 standard deviation method, all sample groups must have a normal distribution. If the sample group has a non-normal distribution, another statistical method must be used to analyze the data for the mean minus 3 standard deviations. To determine if a sample group is normal/non-normal, a p-value can be calculated. If the p-value is greater than 0.05, than the sample group has a normal distribution. If the p-value is less than 0.05, than the sample group has a non-normal distribution.

Table 3

Sample Size Group	<0.010"	0.011"-0.015"	0.016"-0.020"	0.021"-0.025"
Tensile Strength p-Value	0.1298	0.4113	0.6844	0.5197
Normality?	Normal	Normal	Normal	Normal
Elongation p-Value	0.5715	0.0032	0.9166	0.0761
Normality?	Normal	Non-Normal	Normal	Normal

Each test coupon statistical group was analyzed using the process qualification acceptance criteria. The acceptance criteria for this study stipulates that a sample group must pass the minimum acceptance criteria for tensile strength and elongation when 3 standard deviations are subtracted from the sample group mean. If the sample group has a normal distribution, it can be analyzed using this statistical method. If

the sample group has a non-normal distribution, an alternate statistical method can be used which calculates a lower confidence value at 3 standard deviations. The minimum specification for tensile strength is ----------and the minimum specification for elongation is -------.

Table 4

Physical Test	<0.010"	0.011"-0.015"	0.016"-0.020"	0.021"-0.025"
Tensile Strength				
- Average	5.213	5.112	4.825	4.784
- St. Deviation	0.867	0.553	0.809	0.858
Elongation				
- Average	675.914	689.800	621.010	600.553
- St. Deviation	46.233	*49.793*	42.596	55.442
Tensile Strength (-) 3 St. Dev.	2.612	3.453	2.398	2.210
Elongation (-) 3 St. Dev.	537.215	Lower Confidence Limit Value: 623.947	493.222	434.227

* *Non-normal distribution*

7.0 ANALYSIS

The statistical method used in this experiment to calculate the acceptance criteria for shell physical properties was the method used during the HTV Process Qualification. This method determines if particles in the shell have a negative impact on the shell physical properties when compared to the physical property specification.

All test coupon groups were exposed to the manufacturing process consistent with finished devices. All test coupon sample size groups met the required sample size calculation. All test coupon sample groups were determined to be normal, except the 0.011"-0.015" elongation sample group. The mean and standard deviation were calculated for this sample group using the statistical method for non-normal distribution.

When the means and standard deviations of the distinct particle size groups are analyzed using the mean minus 3 standard deviation statistical method, the less than 0.010" group and the 0.011"-0.015" group pass the acceptance criteria for Tensile Strength and Elongation that is currently required for Process Qualification. The

0.016"-0.020" group and the 0.021"-0.025" group pass the PQ acceptance criteria for Elongation, but do not pass the PQ acceptance criteria for Tensile Strength.

8.0 RECOMMENDATIONS

The data collected and analyzed in this report concludes that particles less than or equal to 0.015" in diameter in the shell layers do not affect the shell physical properties to the point in which shells will fail the specification for tensile strength and elongation. It is recommended that a particle size specification for HTV gel shells be set at 0.015". This would allow for shells with a particle less than or equal to 0.015" to be passed for assembly and all shells with a particle greater than or equal to 0.016" would be rejected.

9.0 REFERENCES

7.1 PROC 000308, "Dipping of Moderate Profile Gel Shells"

7.2 QCIC 000114, "Low Bleed Gel-Filled Mammaries Inspection"

7.3 TM 000019, "Determination of Tensile/Elongation Properties of Elastomeric Materials"

7.4 PROC 000218, "Dry Heat Sterilization Procedure For Despatch Ovens"

7.5 PROC 600852, "Low Bleed Mammary Prosthesis Gel Filling and Curing"

7.6 PROC 000310, "Laboratory Method For Cleaning Gel Devices Prior to Testing"

7.7 PROC 500314, "Siltex Becker and Siltex Becker 50 Expander Mammary Prosthesis, Unfilled Sub-Assembly"

7.8 HS33.990715.02, "Engineering Study: HTV Particle Analysis Summary Report"

7.9 HS33.990831.01, "Engineering Study: HTV Particle Specification Analysis"